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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,733	11/08/2001	Donald Carroll Roe	8775	4964

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EXAMINER	
MULLEN, THOMAS J	

ART UNIT	PAPER NUMBER
2632	

DATE MAILED: 06/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/007,733	ROE, DONALD CARROLL	
	Examiner	Art Unit	
	Thomas J. Mullen, Jr.	2632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-20 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 2.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. The patent number associated with related application 09/643,008 should be inserted on p. 8, line 1 of the specification.

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, each of the (i) "bladder monitor", (ii) "wearable bladder monitor", (iii) means for providing "an audible alarm, a tactile alarm or a visible alarm", and (iv) "package", must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Companion et al (US 4,852,578, cited by applicant).

Companion et al teaches an "adaptable operating system" for use by subjects of "varying ages" (col. 2, lines 55-58), wherein an ultrasonic transducer 1 is "positioned on (a) subject...in proximity to (the) bladder" (Abstract, lines 3-4; see Fig. 1), in order to "quantify the relative distention of the bladder" (Abstract, lines 1-2)--i.e., the "state of fullness" of the bladder--whereby the system "recogniz(es) the preliminary need (of the subject) to urinate" (col. 2, last 2 lines). The "relative distention" is compared to an alarm threshold (see Fig. 6), such that one or more alarms (elements 7-10) are generated when the bladder achieves a predetermined level of "fullness" (see the discussion of bladder volumes vs. measured values at col. 7, lines 19-29 and discussion of the Fig. 6 alarm threshold at col. 9, lines 4-8).

In other words, the system of Companion et al "trains" a human subject to "achieve urinary continence by identifying an appropriate continence training opportunity", by carrying out the steps of "obtaining an objective measurement indicative of a state of fullness of the (subject)'s bladder" and "providing a signal to the (subject) or to a caregiver when the measurement equals or exceeds a signal threshold value", as in claims 1, 12 and 20, but fails to specifically teach using their system for training a "child" per se. However, as noted above Companion et al teaches using the system with subjects of "varying ages", i.e. the system provides "adaptability to the requirements of a human subject in a user selectable manner" (col. 2, lines 51-53) and may be "fine tun(ed)" for use with "a wide variety of subjects and conditions" (col. 9, lines 45-48). Further, the general need and/or desirability to "train" children, toddlers, infants, etc. "to achieve urinary continence" is universally known, in order for that child (as he/she grows up), their family, and/or society as a whole to avoid various well-recognized emotional and practical problems (such as those discussed at col. 1, lines 55-65 in Companion et al); in particular, Companion et al mentions the example of an incontinent child being excluded from "preschool programs". Therefore, it would have been obvious to use the system and method of Companion et al to train a "child" to achieve urinary continence, as in claims 1, 12 and 20. Further regarding claim 20, Companion et al characterizes the disclosed system as a "complete electronics package" which is "worn by the subject", i.e. the system is a self-contained "monitor"; it would have been obvious to those skilled in the art that, for commercial purposes, the self-contained electronics device of Companion et al may be "package(d)" with "instructions" for using the device, in order to enhance the marketability and convenience of the device to consumers.

Regarding claims 2 and 13, at the above-noted col. 7, lines 19-29 in Companion et al (comparing bladder volumes vs. measured values), it is taught that an alarm level switch 15A "permits the selection of (one of) sixteen levels", ranging from 9 ("essentially empty" bladder) to 57 (full or essentially full bladder). Thus, Companion et al teaches setting the "signal"/alarm threshold value to correspond to a bladder volume that is "less than a reflexive urination volume" (Companion et al further mentions an "intermediate alarm level" at col. 7, line 53).

Regarding claims 3 and 14, Figs. 4a-c of Companion et al demonstrates a measurement of the bladder at "maximum fullness", i.e. the "reflexive urination volume".

Regarding claim 4, Companion et al further teaches that a "caretaker" associated with the subject (discussed further below with respect to claim 17) can "adjust the alarm level to that point which works best for the individual (subject) involved" (col. 7, last 2 lines and col. 8, first line). What "works best" for the individual or subject is determined, in part, by relying on the physical perceptions of the individual at varying states of bladder fullness (some of which are described at col. 7, lines 34-66, i.e. "the individual can be distracted"; "the individual feels substantial discomfort"; "the individual does not choose to void at the first sensation"; "(the sensations become) annoying"; etc). It follows, then, that an aspect of adjusting the alarm level to what "works best" for the individual or subject which would be required in Companion et al (or, at least, would have been obvious to those skilled in the art to implement therein), would involve the caretaker "querying" the individual or subject as to these physical perceptions or sensations.

Regarding claim 5, the alarms discussed above (elements 7-10) "inform" the subject that "urination is possible or imminent".

Regarding claims 6 and 15, it is an implicit teaching of Companion et al (or, at least, would have been obvious to those skilled in the art to implement therein) that when the alarm signal is given to the subject (or to the "caretaker" of the subject, discussed further below with respect to claim 17), the subject is provided "with the opportunity to urinate into a designated receptacle", since the purpose of the alarm (as discussed above) is to enable the subject to "recogniz(e) the preliminary need to urinate" and then to carry out such urination.

Regarding claims 7 and 16, the "relative distention" of the bladder measured by Companion et al corresponds, directly or indirectly, to at least one of a "dimension", "cross-sectional area" or "volume" of the bladder (Companion et al refers to the bladder "volume" throughout the specification, and refers to bladder "fullness" in Fig. 6).

Regarding claim 8, Companion et al teaches (Fig. 1) each of an "audible" alarm (7), a "tactile" alarm (9), and a "visible" alarm (8) (see the Abstract, last 3 lines).

Regarding claims 9-10 and 18, the collection of elements in Fig. 1 of Companion et al constitutes a "bladder monitor", and transducer 1 is of the ultrasonic/ultrasound type (see the Abstract, line 3; col. 8, lines 17-19; etc).

Regarding claims 11 and 19, as discussed above the bladder monitor in Companion et al is "wearable" by the subject (see col. 7, lines 29-33 and col. 9, lines 9-11).

Regarding claim 17, Companion et al generally describes the subject as being "under test" (col. 3, line 8), and as having a "caretaker" or "caregiver" (whose role is at least partly discussed e.g. at col. 7, line 66 to col. 8, line 2, and col. 9, lines 23-33). The time during which the "bladder monitor" is worn by the subject (see the discussion of claims 11 and 19 above) is inherently a "continenence training period" that is "designated" by the caregiver. Alternately, note that the measurements (Figs. 2-5) are taken over a finite series of "cycles", "bins" or "time ranges" (best shown in Fig. 5c; see col. 5, lines 39-40 and col. 8, lines 29 and 58-59); the measurement periods defined by the "cycles" or "bins" may (individually or collectively) be considered a "continence training period" per se that is "designated" by the caregiver. As a further alternative, it would have been obvious to those skilled in the art to "designate" a "continence training period" per se in order to take the required measurements in Companion et al.

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The remaining art cited by applicant has been considered. Ergas is cited to further show the state of the art.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas J. Mullen, Jr. whose telephone number is 703-305-4382. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 4 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Wu, can be reached on (703) 308-6730. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-3900.

TJM

Thomas J. Mullen, Jr.
Primary Examiner
Art Unit 2632